Section 5

Central Venous Pressure Monitoring

510(k) Summary of Safety and Effectiveness
21 CFR 807.92

5.1 General Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned Subsidiary of C. R. Bard, Inc.]
Address:	5425 West Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700 ext. 7136
Fax Number:	(801) 595-5425
Contact Person:	Lynn M. Kirchoff
Date of Preparation:	July 21, 2005
Registration Number:	1720496
Additional Registration Numbers:	
C. R. Bard	2212754

5.2 Device Information

Device Name:	5 Fr SL PowerPICC™ Catheter
Trade Name:	5 Fr SL PowerPICC™ Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970, Class II Peripherally Inserted Central Catheter
Classification Panel:	General Hospital

Device Name:	6 Fr DL PowerPICC™ Catheter
Trade Name:	6 Fr DL PowerPICC™ Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970, Class II Peripherally Inserted Central Catheter
Classification Panel:	General Hospital

Device Name:	Poly Per-Q-Cath PICC (Peripherally Inserted Central Catheter)
Trade Name:	Poly Per-Q-Cath® PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970, Class II Peripherally Inserted Central Catheter
Classification Panel:	General Hospital

Device Name:	Poly Per-Q-Cath®3 Triple Lumen PICC Catheter
Trade Name:	Poly Per-Q-Cath®3 Triple Lumen PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970, Class II

Classification Panel:	Peripherally Inserted Central Catheter General Hospital

Device Name:	5 Fr SL PowerHohn ™ and PowerLine ™ (Central Venous Catheter)
Trade Name:	PowerHohn ™ and PowerLine ™ Catheters
Common/Usual Name:	Central Venous Catheter
Classification Name:	Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970, Class II
Classification Panel:	General Hospital

Device Name:	6 Fr DL PowerHohn ™ and PowerLine ™ (Central Venous Catheter)
Trade Name:	PowerHohn ™ and PowerLine ™ Catheters
Common/Usual Name:	Central Venous Catheter
Classification Name:	Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970, Class II
Classification Panel:	General Hospital

Subject/Predicate Device Name	510(k)	Clearance Date
5 Fr Single Lumen (SL) Power PICC™	K033389	3/19/2004
6 Fr Dual Lumen (DL) Power PICC™	K050931	6/15/2005
3, 4, 5 Fr Single Lumen (SL) and 4, 5, 6 Fr Dual Lumen (DL) Poly Per-Q-Cath®	K034019	1/21/2004
6 Fr Triple Lumen (TL) Poly Per-Q-Cath®	K043502	1/14/2005
5 Fr Single Lumen (SL) PowerHohn™ and PowerLine™	K050185	5/26/2005
6 Fr Dual Lumen (DL) PowerHohn™ and PowerLine™	K051417	6/30/2005

5.3 Predicate Devices

The predicate devices are:

Device Name:	Cook Turbo-Flo® PICC Catheter
Trade Name:	Cook Turbo-Flo PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970, Class II Peripherally Inserted Central Catheter
Classification Panel:	General Hospital

Device Name:	Cook Triple Lumen Central Venous Catheter
Trade Name:	Cook Triple Lumen Central Venous Catheter
Common/Usual Name:	Central Venous Catheter
Classification Name:	Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970 Central Venous Catheter
Classification Panel:	General Hospital

Predicate Device Name	510(k)	Clearance Date
Cook Turbo-Flo 4 Fr Single Lumen (SL) and 5 Fr Dual Lumen (DL) PICC	K021557	5/30/2003
Cook Triple Lumen 9 Fr Triple Lumen (TL) Central Venous Catheter (CVC)	K021557	5/30/2003

5.4 Device Description

Subject devices:

- Catheters range in French size from 3-5 Fr SL; 4-6 Fr DL and 6 Fr TL
- Catheter usable length ranges from 40 -60 cm.
- Catheters are open-ended catheters extruded from polyurethane material containing barium sulfate for radiopacity.
- The catheter extension legs are polyurethane extrusions. Extension legs are minimum 2.2 in. in length to promote easy application of occlusive dressings. Each extension leg has a thumb clamp.
- The luer hub base material is Isoplast polyurethane.
- The catheter has a reverse taper design
- The user is informed of the gage size in product labeling and it is printed on the luer hub.
- The catheter shaft tubing is marked with depth indicators, with "0" indicated to serve as a reference for the catheter insertion point
- Catheters are provided sterile and are packaged with legally marketed kit components that are preferred by clinicians

5.5 Intended Use of Device

The intended use is the same as the predicate devices.

The Indications for Use was expanded to include ***allows for central venous pressure monitoring. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.***

The Indications for Use statements are as follows:

5 Fr SL and 6 Fr DL PowerPICC™

*The **PowerPICC™** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and **allows for central venous pressure monitoring**. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5mL/sec. The maximum pressure of power injectors used with the **PowerPICC** catheter may not exceed 300 psi. **For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.***

Poly Per-Q-Cath PICC

*The Poly Per-Q-Cath PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling and **allows for central venous pressure monitoring**. For blood therapy, it is recommended that a 4 French or larger catheter be used. **For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.***

Poly Per-Q-Cath Triple Lumen PICC

*The Poly Per-Q-Cath® Triple Lumen PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling and **allows for central***

venous pressure monitoring**. For blood therapy, it is recommended that a 4 French or larger catheter be used. **For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

5 Fr SL and 6 Fr DL PowerHohn™ and PowerLine™

*PowerHohn and PowerLine Catheters are indicated for short or long term access to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, power injection of contrast media and **allow for central venous pressure monitoring**. The maximum recommended infusion rate is 5mL/sec. The maximum pressure of power injectors used with the PowerHohn and PowerLine catheters may not exceed 300 psi. **For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.***

5.6 Technological Comparison to Predicate Devices:

The technological characteristics of the subject devices are substantially equivalent to the predicate devices in terms of intended use, application, user population, basic design, performance, labeling, packaging, and sterilization method.

5.7 510(k) Substantial Equivalence Decision Tree:

New device compared to Marketed Device?

Yes.

Does the new device have the same indication statement as the predicates?

Yes, with expansion of indication to include ***allows for central venous pressure monitoring. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.***

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Yes. The principles of operation are the same as the predicate devices.

Could the new characteristics affect safety or effectiveness?

No. There is no change in design that could affect the safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new types of safety and effectiveness questions

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. Testing was based on recognized and un-recognized standards to evaluate the device's performance:

Are performance data available to assess effects of new characteristics?

Yes. Bench testing was based on the below referenced standards.

- *IEC 60601-2-34:2000(E) Ed.2-Medical electrical equipment- Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment*
- *AAMI TIR:1992- Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring*
- *ANSI/AAMI BP22:1994-Blood Pressure Transducers*

Do performance data demonstrate equivalence?

Yes. Performance data demonstrate that the subject devices are substantially equivalent to the predicate devices

5.8 Conclusion

Subject devices, except for 21 gauge catheter lumens, met the performance criteria of design verification as specified by applicable standards, test protocols and/or customer inputs. As a result the recommendation of catheter lumen of 20 gauge or larger was added to the indications for use. Based on FDA's decision trees, the subject devices are substantially equivalent to the legally marketed predicate devices, the Cook Turbo-Flo PICC and TL Central Venous Catheter, K021557, cleared 5/30/2003.

Subject/Predicate Device Name	510(k)	Clearance Date
5 Fr Single Lumen (SL) Power PICC™	K033389	3/19/2004
6 Fr Dual Lumen (DL) Power PICC™	K050931	6/15/2005
3, 4, 5 Fr Single Lumen (SL) and 4, 5, 6 Fr Dual Lumen (DL) Poly Per-Q-Cath®	K034019	1/21/2004
6 Fr Triple Lumen (TL) Poly Per-Q-Cath®	K043502	1/14/2005
5 Fr Single Lumen (SL) PowerHohn™ and PowerLine™	K050185	5/26/2005
6 Fr Dual Lumen (DL) PowerHohn™ and PowerLine™	K051417	6/30/2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

Ms. Lynn M. Kirchoff
Regulatory Affairs Specialist
C.R. Bard, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K051991
Trade/Device Name: POWERPICC, POLY PER-Q-CATH, 6 FR TL POLY PER-Q-CATH, POWER HOHN AND POWER LINE
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: July 21, 2005
Received: July 22, 2005

Dear Ms. Kirchoff:

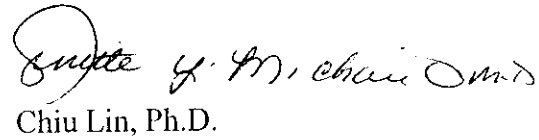
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1.2

Indications for Use

510(k) Number (if known): _____

Device Name: **Single and Dual Poly Per-Q-Cath® PICC**

Indications for Use:

The Poly Per-Q-Cath PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling and allows for central venous pressure monitoring. For blood therapy, it is recommended that a 4 French or larger catheter be used. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K051991

Section 1.2

Indications for Use

510(k) Number (if known): _____

Device Name: **5 Fr Single Lumen and 6 Fr Dual Lumen Power PICC™**

Indications for Use:

The **PowerPICC™** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5mL/sec. The maximum pressure of power injectors used with the **PowerPICC** catheter may not exceed 300 psi. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K051991

Section 1.2

Indications for Use

510(k) Number (if known): _____

Device Name: **6 Fr Triple Lumen Poly Per-Q-Cath**

Indications for Use:

The Poly Per-Q-Cath®3 Triple Lumen PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling and allows for central venous pressure monitoring. For blood therapy, it is recommended that a 4 French or larger catheter be used. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051991

Section 1.2

Indications for Use

510(k) Number (if known): _____

Device Name: **5 Fr Single Lumen Power Hohn™ and Power Line™**

Indications for Use:

PowerHohn and PowerLine Catheters are indicated for short or long term access to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, power injection of contrast media and allows for central venous pressure monitoring. The maximum recommended infusion rate is 5mL/sec. The maximum pressure of power injectors used with the PowerHohn and PowerLine catheters may not exceed 300 psi. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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